

the present invention is to avoid the placement of a balloon distal of the portion of the vessel where treatment is performed and where “biological debris” are created. The present invention provides fluid exchange at a point that is distal of the most distal occlusive balloon. The influx and efflux lumens and ports, specifically those structures recited in independent claims 1 and 34, provide fluid exchange at a region in the vasculature or other regions of the body accessed by a catheter, and does so without introducing an additional balloon distal of the site where fluid exchange occurs. Comparing the systems of Daniels et al. Calderon, and Simpson, a balloon is always present at a point more distal than the fluid exchange.

This distinction is critical when the use of these devices in actual practice is examined – especially for treatment of the area of the vasculature near a lesion. With a two-balloon system, one balloon is inflated proximal to a lesion and the second balloon inflated distal to the lesion. Fluid exchange, stent placement, or other treatment is performed and then the balloons are deflated to re-establish normal blood flow in the patient. Importantly, and necessarily in the two-balloon system, the most distal (second) balloon must be advanced across the site of the lesion upon removal of the embolic particles generated during removal of occlusion catheter. Clinical analyses conclusively establish that this event generates emboli that can harm the patient. Furthermore, as described in the pending claims, the inner catheter moves longitudinally relative to the occluder and can thus move freely along the length of a vessel while the distal occlusion remains in place. This structure cannot exist in the two-balloon systems because the inner catheter carrying the most distal (second) balloon must be inflated and thus cannot also have translatable irrigation capabilities.

In contrast, with the present invention, no balloon is passed across the point where fluid exchange occurs, this is particularly important when treating an area where emboli may be created either during the procedure or when passing a balloon across a lesion. Accordingly, the present invention provides structural features enabling fluid exchange distal of the most distal occluder element present in the system. This distinction is recited in the present claims by noting that reciting both influx and efflux lumens and ports or openings that establish fluid communication to the point distal of the occluder and by defining the occluder element as located at the distal end of the catheter and creating a distal occlusion where fluid exchange occurs in the vasculature distally of any occlusion. This structure is described in Claim 1 a forming a “distal occlusion” to distinguish the two balloon systems.

Also, the influx and efflux ports are defined as in fluid communication with the vessel vasculature defined as distal of the occluder. While Applicants submit that the language of the original claims describes such a system, the present amendment clarifies that the efflux port at the proximal end of the catheter device is in fluid communication with a lumen passage that terminates in an opening distal of the occluder. Claim 34 recites a negative limitation to define the absence of an occluder/balloon in the vessel immediately distal of the treatment site where fluid exchange occurs. New claim 67 specifies that the termination of the fluid communication from the inner shaft at the rinse nozzle provides for rinse fluid to contact the entire distal length of the inner shaft. This limitation also distinguishes the two balloon systems where rinse fluid is contained in the isolated region between the two balloons and cannot contact the outer surface of the inner shaft.

Calderon Does Not Disclose Fluid Exchange Distal of the Occluder.

While Calderon discloses structures for extraction and injection of agents distal to the proximate balloon, no disclosure exists for fluid exchange distal of the second balloon. At column 7, lines 59-61, Calderon notes that, when used for retrograde perfusion, ports 25 and 31 are used for injection and extraction, respectively. Port 31 is clearly proximal of the occluder, balloon 22, and thus does not disclose the efflux port, efflux lumen and opening distal to the occluder as is recited in the claims, as amended.

Functionally, Calderon suffers the serious drawback in the prior art described above that does not enable the user to perform fluid exchange at the site of lesion without dragging a balloon over a lesion in a vessel wall at the conclusion of the procedure. Thus, in the Calderon device, in order to extract fluid through port 31, the distal-most balloon must be passed over a lesion to extract fluid distal of the lesion and must be drawn back across the lesion at the end of a procedure. Each such passage of the balloon generates emboli that then cannot be removed from the vasculature. Thus, because the procedure necessarily required by the structural features of Calderon can achieve fluid exchange at a lesion, but then requires drawing a deflated balloon across the lesion, the potential for generating emboli before contact between the deflated balloon and the vessel wall is still present.

In contrast, with the device of the present claims, fluid exchange can occur distally of the occluder and the risk of generating emboli at a lesion, upon removal of the device, does not exist.

Furthermore, the fluid infusion parameters that are inherent in the design of the invention are different in function than the present invention – this aspect is addressed in connection with the use of the Calderon reference under § 103 below.

Daniels et al. Does Not Disclose Fluid Exchange Distal of the Occluder.

As noted above, Daniels et al. is another two-balloon system, providing fluid exchange between the two balloons that function as occluders to isolate a portion of the vasculature.

Daniels et al. does not provide fluid exchange distal of the inflatable balloon 72. Daniels et al. operates under the same theory as Calderon. As Daniels et al. state:

A related object of the present invention is to provide a catheter device designed for transferring fluid material to or from an isolated vessel segment ...

(Column 2, lines 3-5).

The catheter device of the invention includes a first catheter having a tube with a distal and proximal end, an inflatable balloon carried on the distal end of the tube, a channel extending through the tube and a fluid conduit for supplying fluid to the balloon from the tube's proximal end. A second catheter in the device also provides a tube with distal and proximal ends, an inflatable balloon carried at the tubes distal end,...

(Column 2, lines 10-17).

The second catheter is then threaded through the first catheter and into the vessel until its balloon is positioned adjacent the other end of the segment. Inflating the two balloons isolates the vessel segment. Fluid is then transferred through the device into or out of the isolated segment.

(Column 2, lines 42-47).

As shown in Figure 6 of Daniels et al. (reproduced above), the entire process of fluid exchange occurs proximal of the second balloon 72. There is no efflux port, lumen or opening for irrigation or aspiration distal of the most distal occluder.

Simpson et al. Does Not Disclose Fluid Exchange Distal of the Occluder

Simpson et al is a conventional two-balloon system, similar in design to Daniels et al. and Calderon, but having the ability to employ treatment devices between the two balloons. As in the other two references, the design theory is to create an isolated space within the vessel that is bordered on the distal end by an inflatable occluder. No fluid exchange can occur distally of the occluder because the irrigation and aspiration lumen and ports are not of adequate dimension and are not configured to achieve this purpose. In contrast, the presently claimed invention provides lumens, access ports, and openings distal of the occluder to allow fluid exchange to occur distally of the most-distal occlusion.

A. Because the Structural Elements Enabling Fluid Exchange Distal of the Occluder are Not Disclosed by Daniels et al., Calderon, or Simpson et al., These References Cannot Anticipate Under § 102.

In accordance with MPEP § 2131, “[a] claim is anticipated only if *each and every element* as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” Verdegaal Bros. v. Union Oil of California, 814 F.2d 628, 631, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987) (emphasis added). The disclosure of a claim element in a prior art reference, when relied upon to negate patentability, must also be clear and unambiguous. Further, “[t]he identical invention must be shown in as complete detail as contained in the...claim.” Richardson v. Suzuki Motor Corp., 868 F.2d 1226, 1236, 9 U.S.P.Q.2d 1913, 1920 (Fed. Cir. 1989). Furthermore, and uniquely important in this case is the

requirement that the elements relied on in the prior art reference must be arranged as required by the claim. See In re Bonds, 910 F.2d 831, 832, 15 U.S.P.Q.2d 1566, 1567 (Fed. Cir. 1990).

In this case, rejection of Claims 1, 2, 5, 6, 9, 10, 12, 13, 15, 17, 34, 35, 40, 41, 44, and 48 under 35 U.S.C. § 102(b), as allegedly being anticipated by Calderon, and/or Daniels et al., or Simpson et al. should be traversed by the amendment clarifying that the present claims define a structure providing fluid exchange distal of the occluder.

Without acquiescing in the rejection as phrased by the Examiner, Applicant has amended Claims 1 and 34 to further clarify this aspect of the claimed subject matter of the present invention, specifically to emphasize the presence of a structural element providing fluid communication between the efflux port and an opening distal of the occluder. As noted above, this configuration is advantageous in comparison to the two balloon systems because the fluid exchange can occur at a point that is completely distal to the occluder and, in use, the patient is protected from the generation of emboli during the removal of the distal most balloon.

Accordingly it is submitted that Claims 1 and 34, as amended, as well as the claims that depend thereon, are not anticipated by Daniels et al., Calderon, or Simpson et al. and are in condition for allowance.

B. Claim Rejections – 35 U.S.C. § 103

In accordance with MPEP § 2142, the Examiner bears the initial burden of establishing a *prima facie* case of obviousness. “To establish a *prima facie* case of obviousness, three basic criteria must be met.” See MPEP § 2143. First, some suggestion or motivation in the prior art references or in the knowledge of one of ordinary skill in the relevant art must exist to modify or

combine the references. Second, if the references are combined, a reasonable expectation of success must be shown. Then, finally, all of the claim limitations must be taught or suggested by one reference or a combination of references. Id.

Claims 2, 15, and 16 over Calderon plus Macoviak

In this case, the Examiner rejected Claims 2, 15, and 16 under 35 U.S.C. § 103(a) as being unpatentable over Calderon et al. in view of Macoviak, U.S. Patent No. 6,254,563. It is respectfully submitted that a prima facie case under § 103 cannot be established under this combination because neither reference teaches or suggests a catheter device enabling fluid exchange distal of the occluder. Nor do the two balloon systems allow the catheter carrying the infusion lumen and rinse nozzle to be actuated longitudinally to be translatable relative to the occluder.

Referring to these three claims, claims 2, 15, and 16 further define the invention by specifying that the occluder is inflated, that an inflation lumen is incorporated into a wall of the outer shaft, that the inner shaft lumen is sized and configured for passage of a guidewire, and that a flexible, fluid tight seal exists at the distal end of the inner shaft lumen.

While Macoviak et al. appears to disclose the option of sealing the distal end around a guidewire, the combination with the device of Calderon still would not yield the claimed elements of the present invention because there is no mechanism for fluid exchange distal of the occlusion. It appears that the primary disclosure of Macoviak et al. is intended to supply selective perfusion in the aortic arch, and while a distal occlusion is one alternate, no perfusion distal of the occlusion is contemplated. Thus, even assuming that a combination of Calderon and

Macoviak were operative, the combined device would not feature each element at the claims.

Therefore, no prima facie case exists under § 103.

Claims 3 and 38 over Calderon plus Kletschka.

Claims 3 and 38 recite, in parallel fashion to claims 1 and 34 respectively, that the inflation lumen extends through a separate, parallel, hollow elongated shaft. The Examiner has cited the Kletschka reference in addition to Calderon. While Kletschka appears to disclose a discrete inflation lumen, as above, even the combination of Kletschka and Calderon do not disclose a structure to achieve fluid exchange distal of the occlusion. For the same reasons as above, no prima facie case under § 103 exists for claims 3 and 38 as amended.

Claims 7 and 42 over Calderon et al. plus Booth

Claims 7 and 42 are rejected over Booth et al. in combination with Calderon. Claims 7 and 42 add the features of an open-ended foam in fluid communication with an inflation lumen. While Booth et al. disclose an expanded cell foam that is constructed by exerting a vacuum through a lumen, it is not entirely clear that fluid communication is established. Even so, as above, the combination clearly does not disclose fluid exchanges in a vessel distally of a distal occlusion and these claims are not rendered obvious under § 103.

Claims 8 and 43 over Calderon et al. plus Kletschka and Booth

Claims 8 and 43 depend from claims 7 and 42 and specify the separate inflation lumen of claims 3 and 38. Without acquiescence in the property or operability of the combination;

Applicants submit that a prima facie case under § 103 is not established against the amended claims for the same reasons as cited above.

Claim 36 over Calderon et al. plus Booth

While Booth et al. disclose multiple infusion openings, if the catheter at Booth et al. were combined with Calderon, the combination would be inoperative because there is no exchange of fluid distal of the occlusion. The openings of the Booth et al. catheter would not be extended distally at the occlusion and would not slide longitudinally within the inner shaft as required by Claim 36. Accordingly, no prima facie case against Claim 36 exists based on the combination of Calderon and Booth et al.

Finally, Applicants note the absence of any rationale in the cited references that could lead to a modification of a reference or any combination thereof that would render the present claims unpatentable under either § 102 or § 103. The present claimed invention is different from the combination of elements cited by the examiner from Calderon, Daniels et al, or Simpson because the current claims define a system in which for the following reasons:

The infused fluid enters via the inner lumen and returns to the aspiration port by substantially traveling through the segment of the one or more body vessels that contain the infusion catheter. The infusion catheter, absent of an expandable occlusion mechanism over its distal portion, allows greater access to the more distal portions of the network of body vessels and a preferred distribution of the one or more infusion ports as well as several other advantages. Accordingly, rather than isolate a site between balloons to establish a closed area for fluid

exchange, and a fixed irrigation point, the present invention leaves the distal vasculature open and translates the irrigation mechanism along the inner length thereof.

This differentiates Calderon in several respects. The elements of Calderon create a system with which the flow is directed from the infusion ports to the aspiration ports via one or more paths that are forced by occlusion mechanism (22) to lie outside of the vessel within which the infusion catheter lies. This is because the balloon (22) prevents flow from infusion port (25) to travel directly back to aspiration port (34).

Although Calderon has infusion and aspiration ports and occluding members to produce a flow that is substantially along the vessel segment(s) within which the infusion catheter lies, the inclusion of the second, distal balloon (22) by Calderon renders the system completely incompatible with the present claimed invention because the infused fluid is on the opposite side of the distal occlusion balloon from the efflux port does not describe a suitable implementation of our device, for the aforementioned reasons and others (because it is a dual balloon system).

The same is true of the Daniels et al reference, as demonstrated in Daniels, figure 4, the vent port (38) in the Daniels patent, provides a communication path from the inside of balloon (30) via vent wire (46) to an environment external to the patient (proximal end of (46) in figure 1). The vent port simply provides an escape path for fluid (i.e., air bubbles) within the confines of the balloon (30) to be flushed out when an alternative fluid is injected via balloon supply port (36) and, respectfully, does not appear to provide a path of either supply to or drainage from the treatment site for a fluid that would communicate with the treatment site.

Supply port (36), first catheter (14) and its distal portion (16), and supply port (40) all relate to the same lumen, through which the second catheter can be introduced to the treatment

side. Fluid can be either infused or removed from the treatment site through the lumen of the first catheter, but not both infused and removed through the same lumen at the same time. Central bore (70) of second catheter (68) communicates with the interior of a second balloon (72), and does not provide a second passageway so that approximately simultaneous infusion and aspiration could occur.

Accordingly it is submitted that pending claims, as amended, are believed to be in condition for allowance.

If a telephone call would further prosecution of this case, the Examiner is invited to call the undersigned attorney at (949) 567-6700, extension 7740.

Respectfully submitted,

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